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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/16/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,078

Applicant(s)

LACHARRIERE ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19,20 and 23-37 is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-18, and 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/580,291.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-10, 12-37 are pending. The Amendment filed 5/22/03, Paper No. 14, amended claims 1, 8, 10, 12, 17 and 19-21 and added claims 22-37.

Applicant's amendment to the claims filed 5/22/03, Paper No. 14, is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

Applicant's arguments with respect to the 35 USC 103 rejection of claims 1, 3-10, 12-18 and 21, in the previous Office Action, have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 22 is vague and indefinite, as it is confusing. Claim 22 depends on claim 19, but does not further limit claim 19. Instead claim 22 merely recites the agents recited in claim 19. Was this claim added erroneously or did Applicant leave out an additional limitation?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker et al. (5,039,695) in view of Holick et al. (4,738,643).

The instant invention is directed toward a composition comprising an interleukin-1 antagonist, a TNF-alpha antagonist, or combinations thereof, in an amount to eliminate or alleviate an irritant side effect, an agent selected from alpha-keto acids, beta-keto acids, anthralins, anthranoids, peroxides, minoxidil, lithium salts, antimetabolites, vitamin D, or depigmentation agents, and a cosmetically acceptable medium.

Parker et al. teach a method of using aryl or heteroaryl 1 alkyl pyrrole 2 carboxylic acid compounds in the treatment of interleukin 1 mediated conditions, such as psoriasis, wherein the heteroaryl-1-alkyl-pyrrole-2-carboxylic acid is a heterocycle and is a nitrogen compound having at least one benzene ring. Taught is a cream comprising 4% of an interleukin-1 antagonist (the Pyrrole 2 carboxylic acid), cetyl alcohol (alcoholic solution agent which produces irritant), glycerol monostearate PEG 40, diglycol stearate, polyethylene glycol 400, and purified water. The interleukin-1 antagonists are taught as comprising 0.01-15% of the composition. Oil in water emulsions, oily suspensions, aqueous suspensions, and others are taught as forms of the composition. Preservatives are taught as additional ingredients in the composition, wherein preservatives are antiparasitic agents. The reference lacks an agent which produces an irritant. See Col. 1, line 55-Col. 3, line 20; Col. 7, line 51-Col. 12, line 65.

Holick et al. teach a method of treating psoriasis comprising administering an effective amount of a vitamin D compound to a patient. See abstract.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to add vitamin D compounds of Holick to the composition of Parker et al. because of the expectation of achieving an additive effect of the vitamin D compounds and the interleukin-1-antagonist in treating psoriasis and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

It is respectfully pointed out that the since Parker et al. teach the interleukin 1 antagonists in the preferred amounts recited in the instant claims, Parker et al. teaches an amount "sufficient to eliminate or alleviate said irritant side-effect".

In reference to the intended use recitations in claims 10 and 12, it is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the intended use of the claimed composition is not given patentable weight.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance:

Claims 19-20, 23-37 are allowable over the prior art, as the prior art does not teach a composition comprising a TNF-alpha antagonist in an amount to eliminate or alleviate an irritant side-effect, an agent selected from alpha-keto acids, beta-keto acids, retinoids, anthralins,

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anthranoids, peroxides, minoxidil, lithium salts, antimetabolites, vitamin D or depigmentation agents, and a cosmetically acceptable medium, and does not teach a composition comprising an interleukin-1 antagonist and at least on TNF alpha antagonist in an amount to eliminate or alleviate an irritant side effect, and a cosmetically acceptable medium.

The closest prior art is US 5,039,695. However, this reference is silent regarding TNF-alpha antagonists.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 2, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER